



K051336
RG Medical Diagnostics

JUN 29 2006

510(k) Premarket Notification Summary

Geratherm[®] SOS-Rescue Bag

Common Name – Warming Bag

Classification name- Thermal Regulating System (870.5900)

Predicate Device - ChillBuster[™] Portable Electric Blanket (Thermogear, Inc. K991684)

The following material
presents the 510 (k) Summary
for the Geratherm[®] SOS-Rescue Bag

21130 Bridge Street • Southfield, MI 48034
Phone: 888-596-9498 • Fax: 248-750-0187 • Website: www.rgmd.com

Premarket (510K) Summary

Submitter Information

RG Enterprises, Inc.
(dba) RG Medical Diagnostics
21130 Bridge Street
Southfield, MI 48034
888-596-9498
Date Prepared 04/01/05

Device Name:

Proprietary name: Geratherm SOS-Rescue Bag (Thermamed "Smartcare")
Common name: Hypothermic Therapy System
CDRH Product Regulation: Thermal Regulation System (21 CFR, 870.5900)

Establishment Registration Number: 1835242

Classification: II (DWJ)

Predicate Device:

RG Medical Diagnostics, 21130 Bridge Street, Southfield, Michigan, 48034 has designated The **Chillbuster™ Portable Electric Blanket System, Model 8001**, manufactured by Thermogear, Inc. 18005 Lower Boones Ferry Rd., Togart, OR 977224 as the Predicate Device for the Geratherm SOS-Rescue Bag, manufactured by Geratherm AG, Fahrenheitstrasse 1, D-98716 Geschwenda/Germany.

Statement of Substantial Equivalence:

Geratherm SOS-Rescue Bag is substantially equivalent to:

1. ChillBuster™ Portable Electric Blanket (Thermogear, Inc K991684)

Description of Device:

The Geratherm SOS-Rescue Bag is made up of five major components:

1. Bag: The main functional element is 78.75 inches (200cm) by 31.5 inches (80 cm) comprised of two primary elements:

(a) The bag is constructed like a sleeping bag with an actively warmed upper panel and insulated bottom panel. The upper warming cover uses electrically resistive woven carbon fiber elements to generate warmth. The warming elements are sandwiched between two layers of Dacron® polyester hollow fiber insulating fleece. Lastly, the polyester fleece/carbon fiber layers are encapsulated with a waterproof polyurethane / polyester cloth laminate outside layer. A permanently attached power cable is located near the upper corner of the active warming cover. The free end is plugged into the power control module via color-coded quick-connect power connectors. The top warming cover is permanently sewn along one entire side to the insulated “bottom” panel. This arrangement allows top panel to be folded over the patient and secured once the patient has been placed in a prone position on the bottom panel. The bottom panel has 9 (nine) handholds around its perimeter that lets rescue personnel carry or move a supine patient without the use of a stretcher.

(b) A removable waterproof polyurethane / polyester cloth laminate protective liner is attached to the bag’s inner surface. The protective cover is held in place to the bag’s inner surfaces with Velcro® attachments. This attachment system permits easy removal for machine washing and disinfecting.

2. Control Module: The control module is a impact plastic housing that contains the electronic circuitry. The module regulates bag temperature through a feedback circuit employing two thermistor temperature sensing systems. Operator control is achieved through the use of four buttons located on the face of the module: an on button, off button, a 37° C (98.6°F) select button, and a 42° C (107.6°F) select button. The control module uses LED arrays to display both bag temperature and battery power status. Normal functions are monitored both through visual displays and audible signal. Power sources include the following: the auxiliary battery, an automotive type power supply outlet, or an aircraft power supply outlet. Either 12 volt DC automotive or 24-28 volt DC aircraft power sources may be used to power the unit.

3. Battery: The Geratherm SOS-Rescue Bag uses a sealed lead-acid gel rechargeable battery of 10-ampere hour capacity.

4. Cabling: The Geratherm SOS-Rescue Bag has a power cable permanently attached to the upper corner. The cable attaches directly to the Control Module. The cable supplying power to the power module has a color-coded quick connect on the module end and a connector that fits the auxiliary battery or automotive/aircraft DC power outlets on the other.

5. AC Charger: The Geratherm SOS-Rescue Bag employs a 12 volt, DC, 2-ampere hour output battery charger to charge the battery or maintain full battery status. The charger may be used with either 110 or 240 Volt, 50 or 60 Hertz, AC input electric current.

Intended Use

The Geratherm® SOS-Rescue Bag is designed to prevent and counteract accidental hypothermia in accident victims and patients who are being transported with or without a stretcher, by ambulance, rotary or fixed wing aircraft. Using the Geratherm® SOS Rescue Bag System lowers susceptibility to shock caused by the cold. In addition, patients experience a subjective reduced perception of pain.

Non-Clinical Performance Data

The studies reported in this subsection were conducted by CE-LAB GmbH, iMG gGmbH, TREO Electrooptik GmbH, and TÜV GmbH

Standards: The Geratherm SOS-Rescue Bag has been tested to the following standards:

General Medical Safety:

EMC Specification EN 60601-1-2:2001.

NATO Standard DCS01, DCE01.

Generic Specification of SPAME (Special Purpose Aeromedical Equipment) Issue 3, page 16, No. 62 (vibration).

IEC 60601-1:1990 + A1:1993 + A2:1995

IEC 60601-2-35:1996

EN 60601-2-35:1996

CE 0118

ISO 13485:2003

UL AWM Style 1007 & 1589

UL VW-1 FT

Clinical Performance Data

A formal clinical evaluation was performed at the Mayo Clinic comparing passive warming and active warming using Geratherm resistive carbon fiber electrical warming technology.

Alexander Kober, MD; Thomas Scheck, BS; Béla Fülesdi, MD; Frank Lieba, BS; Wolfgang Vlach, BS; Alexander Friedman, MD; & Daniel I. Sessler, MD ,
“Effectiveness of Resistive Heating Compared With Passive Warming in Treating Hypothermia Associated With Minor Trauma: A Randomized Trial,” *Mayo Clinic Proc.* 2001;76:369-375

Results: Patients who were transported with Geratherm (Thermamed) electric / carbon fiber active warming systems experienced significantly lower degrees of hypothermia than those who were transported using passive warming techniques.

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Verification of Operation Under Non-Laboratory Conditions

The Geratherm SOS-Rescue Bag was tested according to the Operating Manual and was found to prevent or reduce hypothermia by the following organizations:

CE 0118

SAMU 38 – Helicopter Mountain Rescue, Grenoble, France

ADAC Helicopter Helicopter Rescueservice, Munich, Germany

Royal Dutch Army, Helicopter Catastrophe Rescueteam, Netherlands

REGA - Mountain rescue service, REGA – Centre Zürich Airport, Zürich, Switzerland

Conclusions Drawn from Clinical and Non-Clinical Testing

The Geratherm SOS-Rescue Bag performed according to specification and compared favorably to the Predicate Device. No new issues of safety or effectiveness were found to arise in the Geratherm SOS-Rescue Bag when compared to the Predicate Device.

Comparison of Technological Characteristics (SOS-Rescue Bag vs Predicate device)

Features	Geratherm® SOS-Rescue Bag	ChillBuster™ Model 8001
Indications for Use	preventing / counteracting hypothermia	preventing / counteracting hypothermia
Function	low-level distributed heat to patient	low-level distributed heat to patient
Heat Delivery Mechanism	conduction	conduction
Heat Source	resistive carbon fiber cloth in insulated cover	thermal wire in blanket
Electrical Requirements	12 VDC & 24-28 VDC @ 7 Amp	12 VDC @ 3.2 Amp
Heating Element Power	120 W (max)	40 W (approx)
Heat Presented to Patient	37° C (98.6° F) or, 42° C (107.6° F)	105° F
User Heat Output Control	Regulated 37° C or, Regulated 42° C	Un-calibrated continuous 20W-40W
Thermal Temperature Cutoff	37° C (98.6° F) or, 42° C (107.6° F)	105° F
Alarms	Audible and Visual	none disclosed
Circuit Protection	multiple fault sensors, circuit breaker and fused controller	Fused positive battery lead
Internal Diagnostics	Continuous automatic self testing	none disclosed
Safety Agency Approvals	TUV Munich	TUV Rheinland
EMC Compatibility Testing	IEC 601-1-2	IEC 601-1-2
Cross-Contamination Protection	Disposable single use liner	Disposable single use liner
Cytotoxicity	L 929-Proliferation; EN 30993-5,-12; OSI 10993-5,-12; LM SOP 4-06-01	
Controller Diagnostic Display	cover temperature, battery power level, fault detection, fault identification	
Bag Material	polyurethane film and Dacron® Polyester cloth laminate with Dacron® hollow filament fleece interior	Oxford nylon and nylon acrylic
Control Unit Construction	High Impact Polycarbonate	Flame retardant polycarbonate
Bag Cleaning	Machine wash - protective cover. Hand wash bag.	Machine wash and dry
System Weight	9.6 lbs (4.35 kg) /w control unit	8 lbs
Disinfection	Suitable for spray or sponge applied water based disinfectants	No information



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2006

R.G. Enterprises, Inc.
c/o Mr. Ronald G. Letoutneau
President
21130 Bridge Street
Southfield, MI 48034

Re: K051336
Geratherm SOS-Rescue Bag
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (Two)
Product Code: DWJ
Dated: June 21, 2006
Received: June 23, 2006

Dear Mr. Letoutneau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

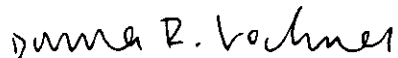
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051336

Device Name: Geratherm SOS-Rescue Bag

Indications For Use:

The Geratherm SOS-Rescue Bag is a temperature controlled electric whole body warming system intended for use in preventing or treating the effects of hypothermia in adults while at the rescue scene or during transport by air or ground to a medical facility.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Lockner
Division Sign-Off
Division of Cardiovascular Devices

510(k) Number K051336

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